IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2014-1185

VASCULAR SOLUTIONS, INC.,

Plaintiff-Appellee,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant-Appellant.

On Appeal from the United States District Court
For the District of Minnesota in Case No. 13-cv-01172-JRT-SER
Judge John R. Tunheim

CORRECTED BRIEF OF APPELLEE VASCULAR SOLUTIONS, INC.

NONCONFIDENTIAL VERSION

Dorsey & Whitney LLP
J. Thomas Vitt
Heather D. Redmond
Suite 1500, 50 South Sixth Street
Minneapolis, MN 55402-1498
Telephone: (612) 340-2600

Attorneys for Plaintiff-Appellee Vascular Solutions, Inc.

January 29, 2014

CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellee Vascular Solutions, Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Vascular Solutions, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Vascular Solutions, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party of amicus curiae represented by me are:

Vascular Solutions, Inc. is a publicly traded corporation; it has no parent corporation; and no publicly held company owns more than 10% of its stock.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

J. Thomas Vitt
Heather D. Redmond
Shannon L. Bjorklund
Forrest Tahdooahnippah

Dorsey & Whitney LLP
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-1498
Telephone: (612) 340-2600
Facsimile: (612) 340-2868

Respectfully submitted,

DORSEY & WHITNEY LLP

Dated: January 29, 2014

By /s/ Heather D. Redmond
J. Thomas Vitt
Heather D. Redmond
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-1498
Telephone: (612) 340-2600

Attorneys for Plaintiff-Appellee Vascular Solutions, Inc.

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CONFIDENTIAL MATERIAL HAS BEEN REDACTED PURSUANT TO A PROTECTIVE ORDER ISSUED BY THE DISTRICT COURT. MATERIAL ON p. 43 IS REDACTED TO PROTECT TECHNICAL DESIGN INFORMATION DESIGNATED CONFIDENTIAL BY BSC. MATERIAL ON p. 55 HAS BEEN REDACTED TO PROTECT COMPETITIVE INFORMATION DESIGNATED CONFIDENTIAL BY BSC

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OTHER AUTHORITIES

STATEMENT OF RELATED CASES

Plaintiff-Appellee's counsel is unaware of any related cases within the meaning of Federal Circuit Rule 47.5.

STATEMENT OF THE ISSUES

I. Did the district court correctly find that VSI is likely to prove that BSC is infringing '032 patent, claims 3, 4, and 13; '413 patent, claims 4, 9, and 10; and '850 patent, claims 3, 4, and 14, by:

A. Construing "**a substantially rigid portion** proximal of and operably connected to . . . the flexible tip portion and **defining a rail structure without a lumen**" by deciding that "without a lumen" modifies "rail structure" and rejecting BSC's argument that the entire substantially rigid portion must be "without a lumen," and

B. Construing "lumen" as "a passageway through which interventional cardiology devices are insertable" and rejecting BSC's contention that a "lumen" can be any cavity or space of any size, where the district court's construction is supported by the patents' claims and specification and the extrinsic evidence?

II. Did the district court abuse its discretion in ruling that VSI is likely to withstand BSC's obviousness challenge, where (a) BSC's prior art combinations do not disclose all elements of the claims, and it would be impossible to use the references as required by VSI's patents, (b) BSC improperly engaged in hindsight and offered no motivation to combine the references, and (c) VSI presented strong

evidence of secondary considerations of nonobviousness, including commercial success, industry praise, and BSC's copying?

III. Did the district court abuse its discretion in finding that VSI demonstrated it would likely suffer irreparable harm absent a preliminary injunction?

STATEMENT OF THE CASE

I. THE PARTIES

VSI is a medical device company focused on bringing clinically unique solutions for vascular diseases to physicians. While VSI has been successful – its 2012 revenue totaled $98 million, and its sales have grown more than 10% in each of the last nine years – it still has a less than 1% share of the U.S. interventional cardiology market. A201 ¶ 4; A253 ¶ 128; A448.

BSC markets a diverse group of medical devices through seven divisions. A415-33; A436. It reported revenue of $7.2 billion in 2012 and is the largest company in the U.S. market for interventional cardiology devices, with a 40% share. A223-24; A436; A448-49.

II. VSI'S INVENTION SOLVED A LONG-STANDING PROBLEM IN INTERVENTIONAL CARDIOLOGY

A. Cardiac Catheterization Procedures And Guide Catheter Limitations[1]

Interventional cardiac catheterization procedures are a minimally invasive alternative to open heart surgery, often performed to clear a blockage (stenosis) in a coronary artery and restore blood flow. A201-03 ¶¶ 6-11. A cardiologist makes a needle puncture in a remote artery to gain access to the arterial system. A guidewire is inserted through the needle, after which the needle is removed and an introducer sheath is inserted over the guidewire. A guide catheter is inserted through the introducer sheath up the patient's aorta and into the beginning (ostium) of the coronary artery. Medical devices such as stents may then be delivered over the guidewire and through the guide catheter's lumen to reach the blockage for treatment. A203-05 ¶¶ 9-11.

A guide catheter must be sufficiently rigid to maintain its distal curve and position at the ostium of the coronary artery. The guide catheter also must provide sufficient "backup" support to keep from moving backwards and becoming dislodged as medical devices are pushed through a tortuous coronary artery and across a stenosis. Without both guide catheter rigidity and backup support, medical devices may not be able to enter the coronary artery or cross the stenosis,

[1] A more detailed description of the technology, including diagrams and photographs, is provided in the Root Declaration. A200-11 ¶¶ 5-20.

causing the procedure to fail. Failure to securely place the guide catheter most often occurs in challenging cases where the anatomy is tortuous or the stenosis is severe, which are precisely the cases where treatment is most needed. A207-08 ¶¶ 14-15.

B. Prior Attempts To Solve Guide Catheter Limitations

While it would be desirable to insert the guide catheter deeper into the coronary artery to provide stronger positioning and backup support, because of the guide catheter's curve and rigidity, it generally cannot be safely "deep seated" (extended past the ostium). A208 ¶ 15. One method used to provide safe deep seating is the "mother and child" guide system. This involves inserting, for example, a 120-cm "child" guide catheter with a relatively flexible and straight distal tip through a standard, 100-cm "mother" guide catheter. Because the child catheter is flexible and straight, it can safely extend beyond the ostium (where the mother catheter is positioned) and deep into the artery to provide additional backup support. A208-09 ¶¶ 16-17.

The mother and child guide system has several drawbacks. First, the system requires two hemostatic valves: one to seal the mother and another to seal the child. Second, the combination results in a 120-cm long guide catheter, which limits the sites that can be treated (most devices are designed for 100-cm guide catheters). Third, to insert or remove the child catheter, all previously inserted

devices, including guidewires, must be removed. As a result, the mother and child system was rarely used. A209 ¶ 18.

C. Over-The-Wire And Monorail Systems

The mother and child guide system is an example of over-the-wire ("OTW") construction. An OTW catheter has a lumen that runs the entire length of the catheter and is used for delivery of the catheter over a guidewire and into the coronary artery. Because an OTW catheter is generally between 100cm and 150cm long, it requires a long (260-300cm) guidewire, requiring two operators to control both ends of the catheter during deployment. A210 ¶ 19.

Another type of catheter is referred to as a monorail, rapid exchange, single operator, or sliding rail catheter. All refer to the same type of construction, having a relatively short (generally 20-40cm) distal lumen used to deliver the catheter over a guidewire, attached to a longer and stiffer proximal rod used to push and retract the catheter but running independent of the guidewire. Monorail construction allows the use of shorter guidewires and a single operator for delivery. A211 ¶ 20; A256-60.

D. VSI's "Game-Changing" GuideLiner Catheter

In 2004, VSI began working on a new idea for a guide extension catheter that would provide "mother and child" guide extension without the disadvantages of OTW construction. That idea became GuideLiner, commercially introduced in

2009, which was the first commercial device to provide the advantages of guide extension with the ease of monorail delivery. A211-12 ¶ 21.

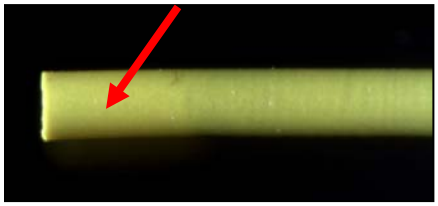
VSI's GuideLiner catheter

GuideLiner consists of a flexible, tubular portion with a lumen, a substantially rigid portion with a pushrod, and a transitional collar section between them. A212 ¶ 23.

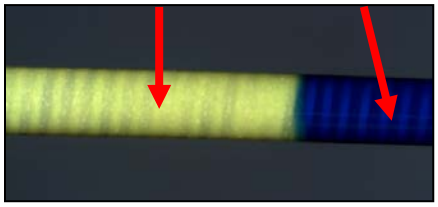
1. GuideLiner's Flexible Portion

The distal end (the left side above) of GuideLiner is a relatively flexible tube with a lumen. The distal end has three zones: a very flexible yellow tip, a less flexible yellow coil reinforced portion, and a further less flexible blue portion made from stiffer polymer. A212 ¶ 22. GuideLiner's flexible portion is inserted through the distal end of the guide catheter so that the distal portion is "deep-seated" in the coronary artery.

GuideLiner
very flexible tip

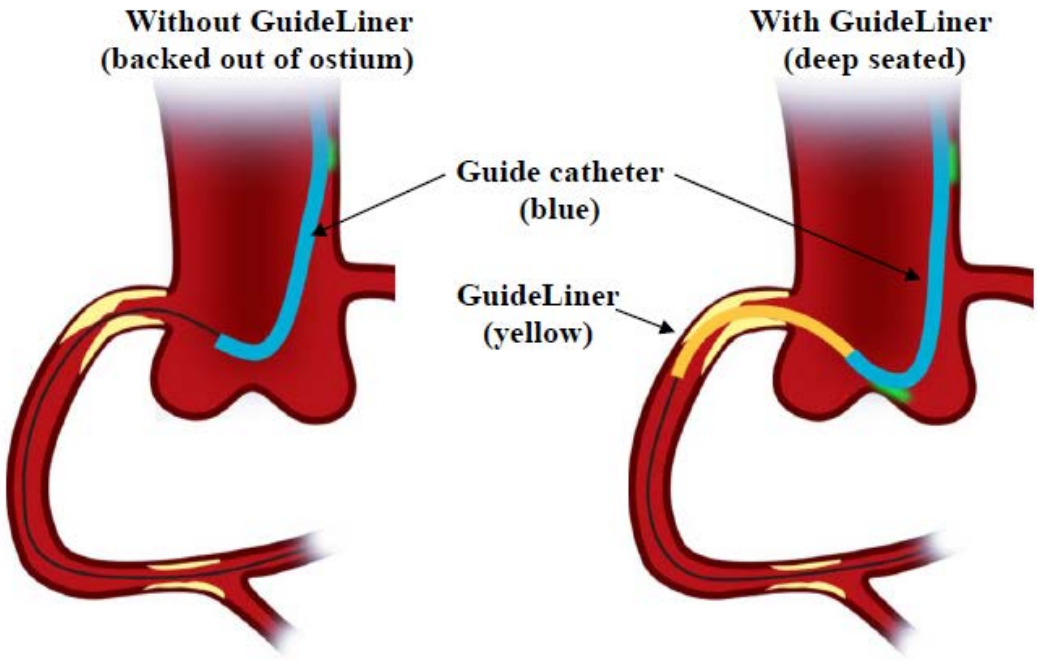


Coil reinforced portion
More flexible Less flexible

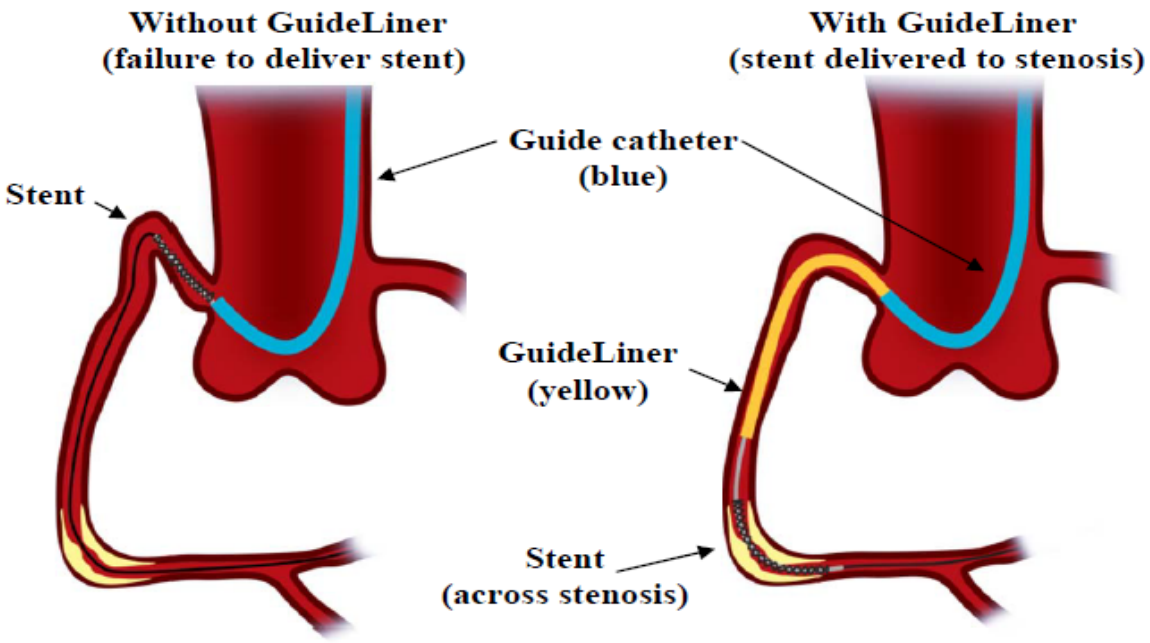


By extending GuideLiner's flexible portion past the end of the guide catheter and

into the coronary artery, GuideLiner provides effective deep seating without the risks (e.g., vessel perforation) associated with deep seating standard guide catheters. In the figure below on the left, a guide catheter has backed out of the coronary ostium. On the right, GuideLiner is deep seated in the coronary artery, providing a secure passageway to deliver devices deep into the coronary artery.



A213-14 ¶¶ 27-28. Deep seating of GuideLiner also allows stent delivery in previously impossible procedures. In the figure below on the left, the stent cannot navigate the artery's sharp downward angle to reach the stenosis. On the right, use of GuideLiner's flexible extension changes the artery's sharp angle into a gentle curve, allowing the stent delivery to the stenosis.



A215 ¶ 29.

2. GuideLiner's Substantially Rigid Portion

The proximal portion of GuideLiner is a substantially rigid pushrod. The proximal end of the pushrod is embedded into a tab to prevent it from being inadvertently pushed too far into the guide catheter during deployment. A213 ¶¶ 24-25.

GuideLiner substantially rigid pushrod

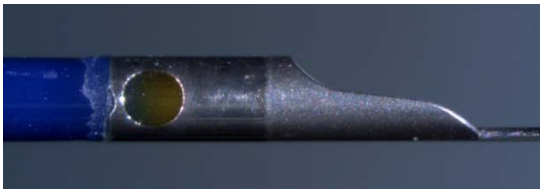
GuideLiner's monorail construction provides multiple advantages over the OTW construction used in "mother and child" systems. Because only the pushrod

extends through the hemostatic valve, a second hemostatic valve is unnecessary and device length is not limited. The monorail construction also allows guidewires previously placed in the artery to remain in place while delivering GuideLiner. A215-16 ¶ 30.

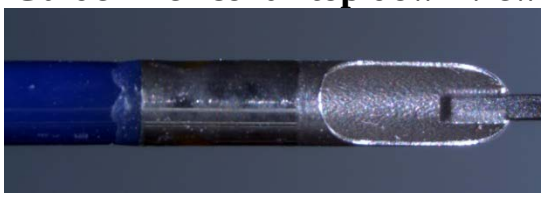
3. GuideLiner's Transition Collar

GuideLiner's flexible portion is joined to the substantially rigid pushrod with a transitional collar portion. The collar allows devices such as stents to enter the flexible portion when delivered through the guide catheter. A212-13 ¶ 23.

GuideLiner collar side view



GuideLiner collar top down view



VSI's collar has a side opening with a non-perpendicular entry angle, allowing for easy entry of devices and transmitting force from the relatively small pushrod to the flexible tube. The angled opening directs the pushrod's advancement force to the catheter circumferentially and in the intended direction of travel of the guide catheter extension, resulting in advancement of the flexible tube through the guide catheter without jamming or twisting. A1091-92 ¶ 18. The shaping of the entry to the flexible tube also assists in allowing entry of an interventional cardiology device into the flexible tube portion, by maximizing use of the space inside the guide catheter, so that there is no obstruction. A1092 ¶ 19.

E. VSI'S GuideLiner Is Clinically And Commercially Successful

Until BSC's Guidezilla, VSI's GuideLiner was the only guide extension catheter available worldwide that provided the benefit of rapid exchange. A219-22 ¶ 44; A246-47 ¶ 107; A334-385. Cardiologists hail GuideLiner as a "game-changing device" and a substantial advance in interventional cardiology, describing the clinical benefits of GuideLiner as allowing them "to treat arteries previously deemed untreatable" and "to successfully complete previously unimaginable interventions." A220 ¶ 44(a); A222 ¶ 45; A334-35; A411-14. According to users, because of GuideLiner, "impossible" cases have been made possible, allowing patients to avoid invasive coronary bypass surgery. A220-21 ¶ 44 (b), (f); A336-40; A369-73. Multiple journal articles have been published and medical symposia held on GuideLiner. A219 ¶ 43; A329-409.

By promoting these clinical benefits, VSI created a new $20 million market that continues to grow. A201 ¶ 4; A247 ¶ 110. GuideLiner is VSI's fastest growing product, and after just three years, GuideLiner was on track to be VSI's highest-selling product. A218 ¶¶ 39-41. In addition, GuideLiner's one-of-a-kind nature and substantial utility make it VSI's most visible product, opening doors for VSI's sales force to many new customers. A218-19 ¶ 42; A249 ¶ 115; A1309-10.

III. VSI'S GUIDELINER PATENTS

On May 3, 2006, VSI filed a patent application on the GuideLiner invention. The application led to three U.S. patents: No. 8,048,032 ('032 patent) (device), issued November 1, 2011; No. 8,142,413 ('413 patent) (method for using the device), issued March 27, 2012; and No. 8,292,850 ('850 patent) (system comprised of the device and a standard guide catheter), issued October 23, 2012 (collectively, "VSI's patents"). A217 ¶¶ 32-36; A52-116.

VSI's patents have independent claims broadly claiming the flexible tubular portion and the substantially rigid portion. For example, '032 patent, claim 1 claims the flexible tip portion as follows:

> a flexible tip portion defining a tubular structure having a circular cross-section . . . defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable . . .

A70. Claim 1 also claims the substantially rigid portion as follows:

> a substantially rigid portion proximal of and operably connected to . . . the flexible tip portion and defining a rail structure without a lumen . . .

Id.

The district court found '032 patent, claims 3, 4, and 13, '413 patent claims 4, 9, and 10, and '850 patent claims 3, 4, and 14 were likely valid and infringed. These dependent claims add limitations covering the transitional collar shapes and its ability to receive interventional devices while inside the guide catheter. Claim 3

of the ‘032 patent claims the collar by adding to claims 1 and 2:

> the proximal portion of the tubular structure further comprises structure defining a proximal side opening . . . to receive an interventional cardiology device in the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

A70-71. Dependent claim 4 further modifies claim 3, adding:

> wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.

A71. Dependent claim 13 depends from claim 11, adding:

> the substantially rigid portion further includes a partially cylindrical portion defining an opening . . . that is adapted to receive an interventional cardiology device . . . while the device is inserted into the continuous lumen [of the guide catheter].

Id. Dependent claims 3, 4, and 14 of the ‘850 system patent are similar to the ‘032 dependent claims. A114.

Dependent claims 4, 9, and 10 of the ‘413 method patent are worded somewhat differently, but add to the independent claims the requirement of a “side opening” and “extending the interventional cardiology device through a proximal side opening . . . while the proximal portion remains within the lumen of the guide catheter.” A93.

IV. BSC COPIES GUIDELINER AND INFRINGES VSI’S PATENTS

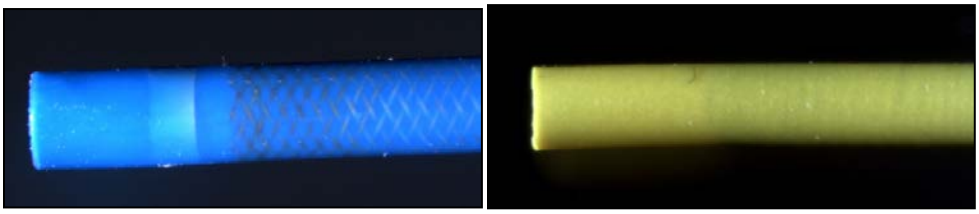
VSI heard rumors that BSC was developing a competing product, and in October, 2012 VSI’s CEO, Howard Root, sent copies of VSI’s patents to BSC. BSC did not respond. In April, 2013, VSI learned that BSC was testing Guidezilla

on a patient. VSI wrote again, asking for a Guidezilla sample and for any analysis that BSC had performed with respect to VSI's patents. BSC again did not substantively respond. In May, 2013, VSI obtained a sample Guidezilla device from another source. A223-27, ¶¶ 50-63; A457-58; 465-93.

Guidezilla is a nearly identical copy of GuideLiner. A230-37 ¶¶ 69-79; A523-32. All three parts – flexible tip portion, substantially rigid portion, and transitional collar – of Guidezilla are essentially the same in construction, dimension, and function as those sections of GuideLiner.

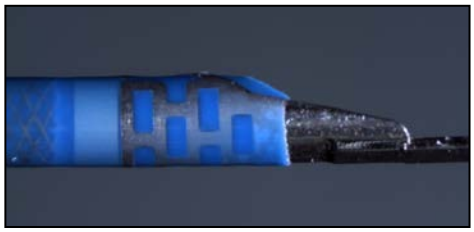
Both Guidezilla and GuideLiner have a nearly identical (but different colored) flexible tip portion made of a 25 cm long tubular structure, with nearly identical inner diameters. A231-33 ¶¶ 71, 75; A524; A529.

Guidezilla flexible tip **GuideLiner flexible tip**



Both Guidezilla and GuideLiner V1 have a metal collar section that transitions the flexible tip to the substantially rigid pushrod by using a tapered cut. A232 ¶ 72; A530.

Guidezilla collar



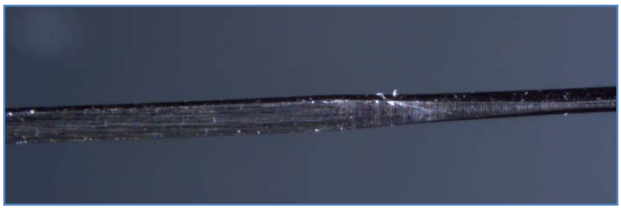
GuideLiner V1 collar

Both Guidezilla and GuideLiner have a substantially rigid pushrod constructed of stainless steel proceeding from the collar on the distal end to a plastic tab on the proximal end where it is embedded and sealed. A232 ¶ 73; A531. Guidezilla's pushrod is formed from a hypotube, with the final 2cm of the distal end pounded flat and welded to the collar. A1183-84; A1255. Although entirely closed on both ends, a functionless space about the width of a human hair remains within Guidezilla's hypotube pushrod. A1103 ¶ 44; A240-41 ¶ 90. BSC stated that its hypotube pushrod has the "[s]ame material composition" and "same function" as GuideLiner's proximal shaft. A1263.

Guidezilla substantially rigid portion

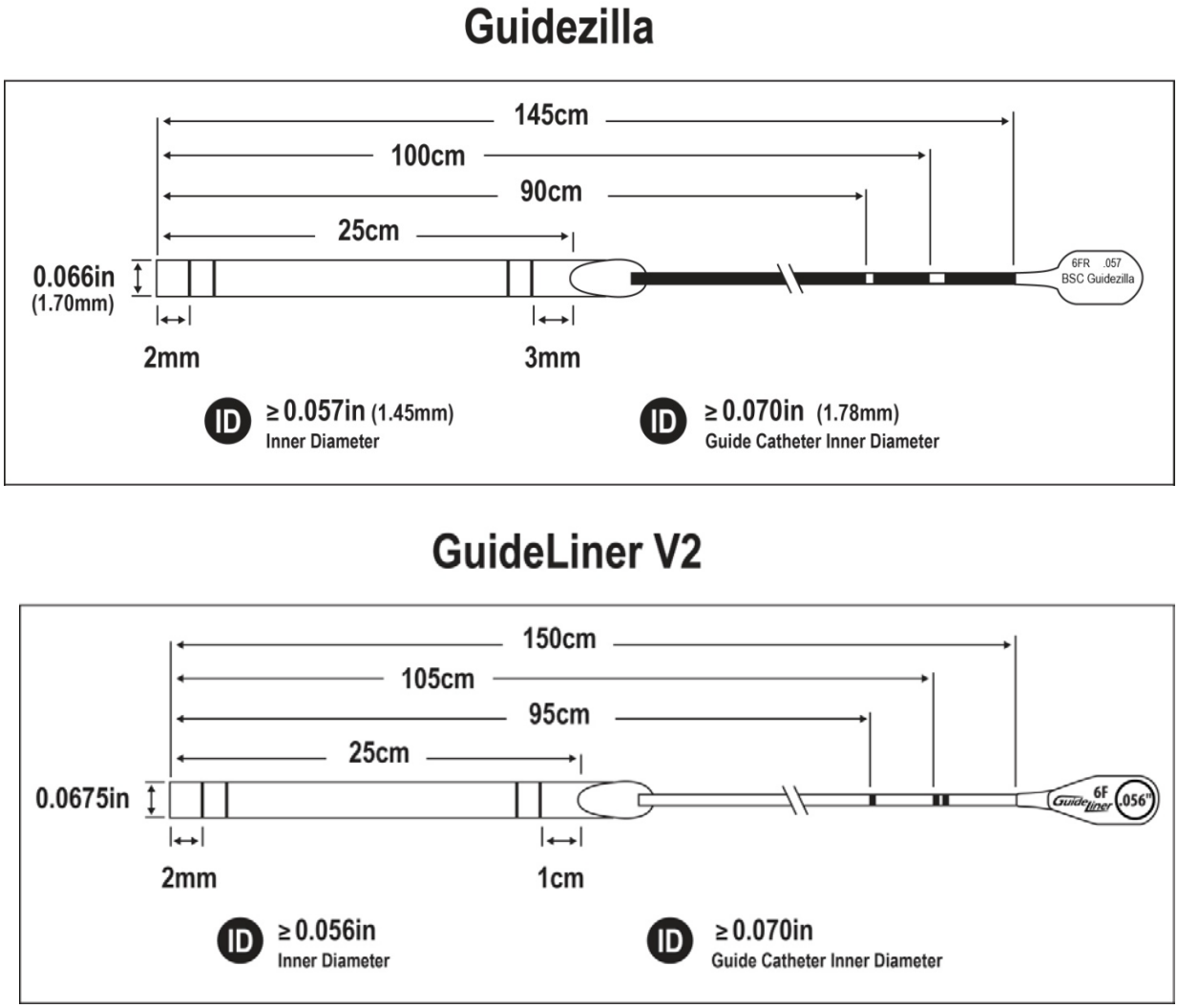
GuideLiner substantially rigid portion

Guidezilla pushrod



GuideLiner pushrod

BSC also copied the construction and dimensions of GuideLiner, as shown below.



A230-36 ¶¶ 68-79; A523-32.

Root, a GuideLiner inventor and an expert in the technology, compared Guidezilla to the claims of VSI's patents and determined that Guidezilla met all limitations of 43 claims of VSI's patents. Guidezilla has both the "flexible tip portion" and the "substantially rigid portion" required by the patents' independent

claims. A238-39 ¶¶ 84-85; A534-37; A651-55; A666-69. Guidezilla also has the transitional collar, as claimed in the nine dependent claims supporting the injunction. A40; A539-41; A548; A657; A660-62; A670-72; A678-79. Root's analysis is described in detailed claim charts submitted to the district court. A226-27 ¶ 61; A230-39 ¶¶ 68-87; A533-551; A648-81.

Having received no response to its letters, VSI filed its Complaint on May 16, 2013. A117. VSI filed its preliminary injunction motion on June 10, 2013.

V. BSC'S INFRINGEMENT WAS CAUSING SUBSTANTIAL IRREPARABLE HARM

VSI submitted evidence to the district court establishing that BSC's infringement was likely to lead to:

- irreparable price erosion, given BSC's much larger size and ability to bundle Guidezilla with other products, A248-49 ¶¶ 112-14; A520-22;
- loss of associated sales of other VSI products, A249-50 ¶¶ 115-16;
- irreparable distraction of VSI's sales force, when VSI is forced to devote substantial resources to deal with BSC's competition, 247-48 ¶ 111;
- lack of profits to fund new R&D projects, required for a company of VSI's size to continue to grow, A250-51 ¶¶ 117-19;
- sales force attrition, historically resulting from lower commissions and bonuses, causing additional training expense and reduced productivity, A251-53 ¶¶ 120-27;
- loss in market exclusivity, changing VSI's reputation from innovator to competitor, A253 ¶ 128; and

- a decline in VSI's 10%+ annual growth rate, historically causing a stock price decline and making it more difficult to attract employees and make acquisitions, A253 ¶¶ 129-30.

VI. BSC'S DEFENSES

A. BSC's Noninfringement Defenses

BSC says that its noninfringement arguments below were based on the meaning "of two different claim terms." BSC Br. at 3. In fact, both arguments were based solely on BSC's proposed construction of the independent claims' "without a lumen" limitation. A700-05. BSC argued that "without a lumen" in the claim limitation "substantially rigid portion . . . defining a rail structure without a lumen" modifies "substantially rigid portion," rather than "rail structure." Thus, according to BSC, the collar's lumen brings Guidezilla outside the scope of the claims.

BSC also argued that Guidezilla's hypotube has a lumen and therefore falls outside the claims' scope. But the hypotube's "space" is about the width of a human hair, and no space exists in the distal 2cm where it is crushed prior to attachment to the collar. A240-41 ¶ 90. BSC concedes that there is no opening on either proximal or distal end for any item, much less a medical device, to be passed through the hypotube. A1183-84; A1254-55.

B. BSC's Invalidity Defense

BSC also asserted an invalidity defense in its opposition, based on the combination of its own Adams patent and one or more of Alt, Steinke, or Verbeek.

1. The Adams Patent

BSC bases its obviousness defense primarily on Adams, an expired patent BSC acquired nearly twenty years ago.

Adams discloses a flexible tube directly attached to a pushrod. A1087 ¶ 9. In use, the tube's distal end extends out of the guide catheter, providing "relatively easy and accurate exchanges of 'non-over-the-wire' catheters, guide wires and other coronary treatment devices," 4:41-44, "a conduit for drug delivery," 3:7-8, and for "aspirating thrombus from a coronary vessel," 3:19. A748.

BSC concedes that Adams does not disclose the collar transition claimed in the nine dependent claims at issue. A1169. Adams does not disclose a proximal side opening for receipt of interventional devices while within the lumen of the guide catheter, as required by '032 patent, claims 3 and 13; '850 patent, claims 3 and 14, and '413 patent, claims 4, 9, and 10. Adams also does not disclose an opening at the proximal end of the tube that includes a partially cylindrical portion, as required by '032 patent, claims 4 and 13; '850 patent, claims 4 and 14; and '413 patent, claims 4 and 10. Instead, Adams describes two types of structures at the proximal end of the tube: a funnel and a balloon. A1085-87 ¶¶ 6-8. The funnel structure is shown in these Adams figures:[2]

[2] All labels have been added to the figures.

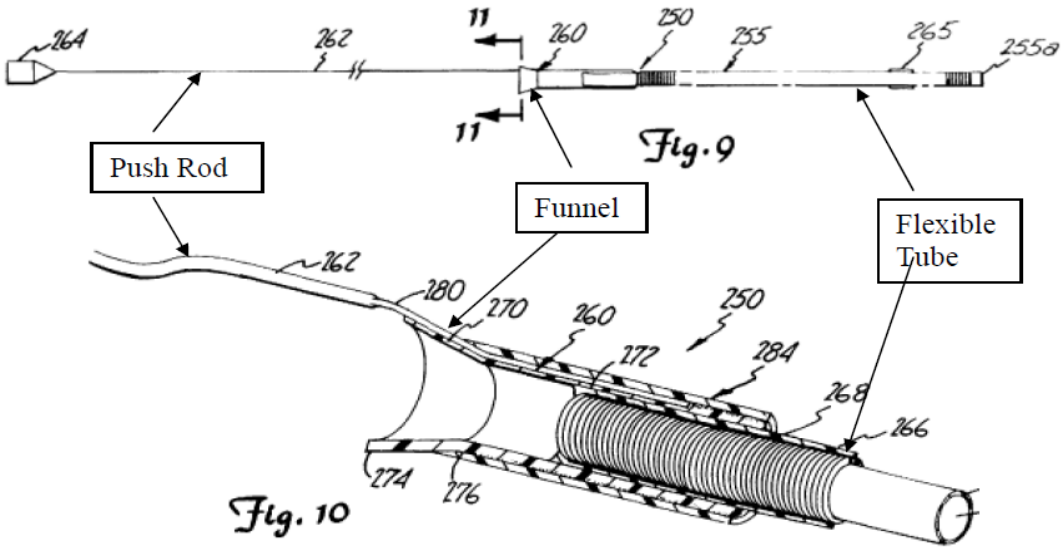
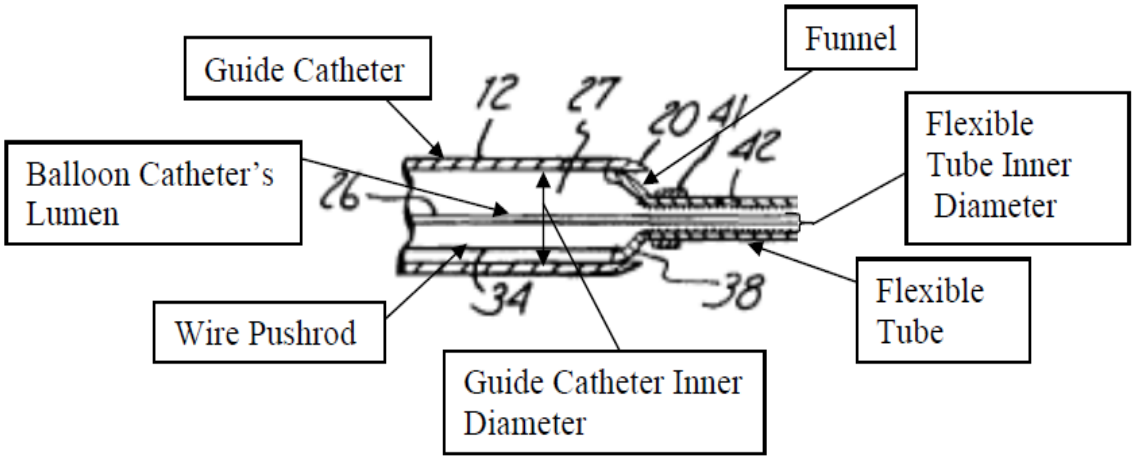


Fig. 9

Fig. 10

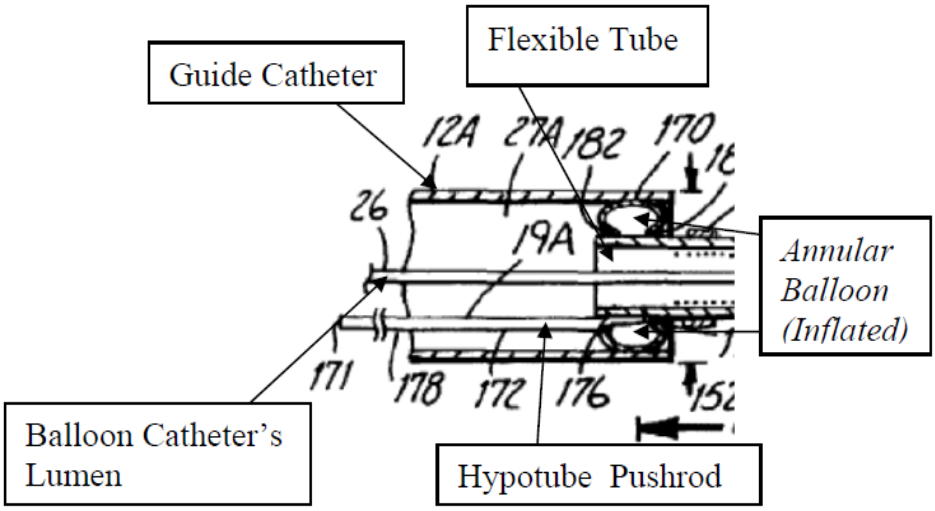


Excerpt from Fig. 2

A1085-86 ¶ 7. The funnel's "close fit" with the guide catheter "provides a seal to facilitate the flow of liquids (such as dye and drugs) through the guide catheter and the tube." A754, col. 16:7-8.

Adams's other connection uses an annular balloon mounted at the flexible tube's proximal end. When inflated, the balloon seals the tube's end to the guide

catheter's inside to allow fluid injections or aspiration, as shown in this Figure 3 excerpt:



A1087 ¶ 8.

In both designs, Adams discloses a flexible tube opening perpendicular to the guide catheter's axis. Both designs lack any "side opening" or transitional structure to allow for gradual delivery of interventional devices into the flexible tube. The Adams "pushrod" pushes directly at just one location on the flexible tube at the attachment point. A1087 ¶ 9. The Adams design can lead to twisting or jamming during advancement, causing problems with pushability when inserted into a guide catheter. A1090-91 ¶¶ 16-17.[3]

[3] Root provided to the district court a detailed description of the Adams patent and its problems. A184-91 ¶¶ 5-17.

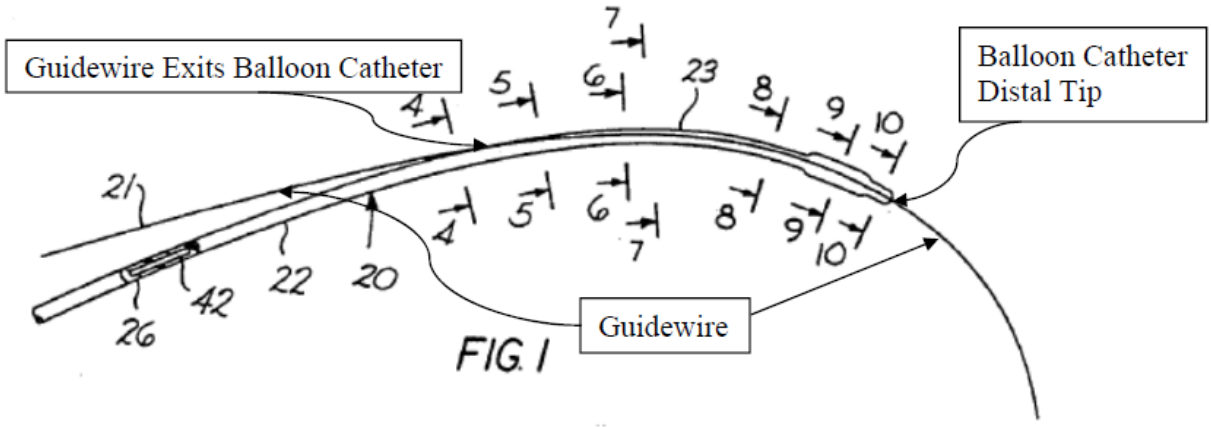
Adams acknowledges delivery problems, stating that it must be inserted into the guide catheter concurrently with another device, or over an already-inserted balloon catheter. A753, col. 16:16-20. While Adams blames the problem on tube flexibility, A747, col. 2:58-62, it is the direct connection between flexible tube and pushrod and lack of collar that impede delivery. A1091 ¶ 17. Thus, when BSC created Guidezilla, it copied GuideLiner's side opening collar instead of Adams' funnel or balloon concept. A527.

2. Verbeek, Steinke, and Alt

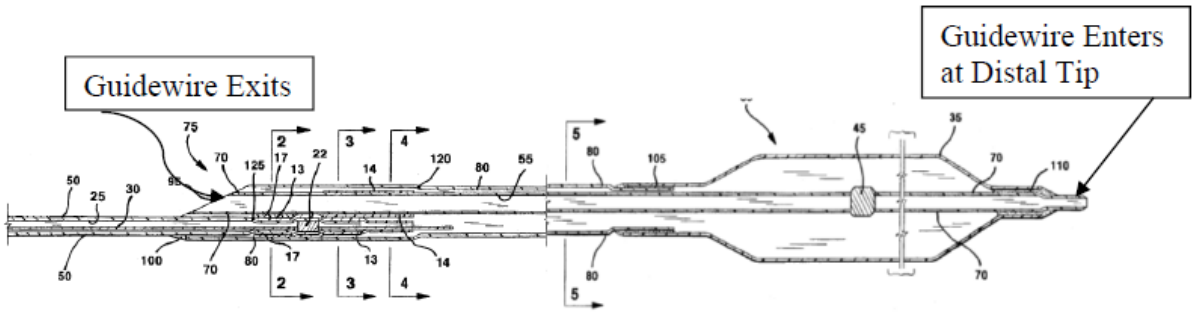
BSC relied below on three patents to supply limitations it admits are missing from Adams. BSC relied on the declaration of a former BSC employee, Vrba, to describe the content of the prior art. However, Vrba admitted that he performed no independent analysis of the prior art to render an opinion on obviousness. BSC's lawyers selected the references for him, and he read only the portions to which he was directed. A1161-63; A1170. Vrba then offered the conclusory opinion that Verbeek, Steinke, and Alt each disclose the missing elements of the dependent collar claims, namely proximal side openings adapted to receive interventional cardiology devices while inside the guide catheter lumen, along with the tapered shape of the collar. A805 ¶ 3.

Alt, Steinke, and Verbeek do not disclose the missing elements. All disclose rapid exchange balloon catheters. A physician threads the catheter's distal tip over

a guidewire, outside the body. As the catheter slides over the guidewire, the guidewire *exits* the guidewire lumen, A1172-74; A1177; A1179-81, while still outside the body. The physician then pushes the balloon catheter into the guide catheter in the artery. The guidewire is typically 0.014 inches, and the guidewire lumen is 0.016 or 0.017 inches. A1171. The figures below show Alt and Verbeek, with the ports that BSC's expert Vrba claims could function as a side opening for receiving interventional devices while inside a guide catheter:



Alt Figure 1



Verbeek Figures 1B, 1C

A1099 ¶ 34; A1096 ¶ 29. Steinke's depiction (Figure 1) is similar to Alt's. A1097 ¶ 31.

The references disclose only sloped exit ports on balloon catheters, all of which are quite different in design, function and utility from VSI's invention. They say nothing about guide extension.

BSC's only evidence of a motivation to combine Adams with Verbeek/Steinke/Alt is again found in Vrba's declaration. There, Vrba offers the conclusory opinion that persons of ordinary skill would have been motivated to combine the references, "because they all address the delivery of devices for interventional cardiology and treatment of vascular disease." A822-23. Neither Vrba nor BSC provided any other reason why one of ordinary skill would have thought to take the tiny, sloped *exit* port from Alt/Steinke/Verbeek, convert and enlarge that exit port into an entrance collar, modify it so it meets the limitations of all nine claims, and use it to replace the perpendicular direct connection between the pushrod and flexible tube in Adams.

VII. BSC HAD A FAIR OPPORTUNITY TO PRESENT ITS DEFENSES

BSC repeatedly accuses VSI of making new arguments in its preliminary injunction reply, using that accusation as an excuse for BSC's reliance on evidence and arguments it failed to present to the district court. *E.g.*, BSC Br. at 4, 16, 38,

42. Contrary to BSC's accusations, it had a full and fair opportunity to litigate its validity challenge to all asserted claims, and in fact did so.

BSC acquired the Adams patent years ago. Yet, BSC failed to provide VSI notice of Adams in response to numerous communications, dating back to August 2012. A224 ¶¶ 51-52; A226 ¶ 60; A458; A466; A553-54; A1114 ¶¶ 5-8. During meet and confer communications before VSI's motion, BSC raised only its claim construction defense. A1114 ¶¶ 7-9; A553-54. VSI had no knowledge of Adams until after VSI filed its opening brief. A1114 ¶ 9; A1083-84 ¶ 3.

While BSC now asserts that VSI's infringement analysis "focused exclusively" on independent claim 1 of the '032 patent, VSI's brief alleged infringement of 43 claims, providing detailed claim charts explaining infringement of each claim, including those relied on by the district court. A533-51; A648-81.

BSC responded that *all* of VSI's claims were invalid, raising Adams for the first time, with Verbeek, Steinke, and Alt. In its reply, VSI focused on the dependent collar claims, because in VSI's view BSC had not made even a colorable validity challenge to those claims. Root's second declaration explained why Alt, Steinke, and Verbeek did not disclose the dependent claim elements, and why those claims were not likely to be found obvious at trial. A1083-1102 ¶¶ 2-42; A1067-78.

At the hearing, BSC attempted to make a new argument based on the Klein patent. Klein was not discussed in BSC's brief or Vrba's declaration, and BSC did not make Klein part of the record, either at the hearing, or in the three months before the court issued its order.

VIII. THE PRELIMINARY INJUNCTION ORDER

The district court entered its order on December 9, 2013. A1-41. On claim construction, the district court concluded that "without a lumen" modifies "rail structure" and "rejected a construction that would require the entire substantially rigid portion to have no lumen" explaining that its conclusion was "supported by the words of claim 1, the words of the dependent claims, and the prosecution history." A25. Relying primarily on intrinsic evidence, the court determined that "a person having ordinary skill in the art of cardiac catheterization procedures/interventional cardiology would understand 'lumen' as used in the phrase 'rail structure without a lumen' means 'a passageway through which interventional cardiology devices are insertable.'" A29-30. On that basis, the court found that VSI is likely to prove infringement of the asserted claims.

With respect to invalidity, the district court found that Alt/Steinke/Verbeek disclosed only "angled exit ports" for a guidewire, not entrances for devices such as stents. Thus, the court concluded that the openings "do not indicate that the feature is being used for the same function as the collar in Vascular's patents."

A34. The court also found that BSC did not identify adequate motivation to combine the references. A35. Finally, the court found that VSI presented evidence of "multiple objective indicators of nonobviousness including commercial success, praise by others, and copying" by BSC. *Id.* On those bases, the court concluded that VSI demonstrated that the dependent collar claims were likely to withstand BSC's validity challenge. *Id.*

The district court also concluded that VSI had demonstrated irreparable harm caused by BSC's infringement. Specifically, the court found evidence of price erosion and lost sales to BSC. A37. It also determined that the patented technology is "central to" VSI's business, and that "the harm to [VSI] in the absence of an injunction is likely to be greater than that caused to [BSC] by an injunction." A39.

SUMMARY OF ARGUMENT

The district court correctly found that VSI satisfied the four-factor preliminary injunction test, by establishing that it was likely to succeed on the merits, that it was likely to suffer irreparable harm in the absence of preliminary relief, that the balance of harms tips in its favor, and that an injunction was in the public interest. A21 (quoting *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1373-74 (Fed. Cir. 2012)). On appeal, BSC concedes that the balance of harms

weighs in favor of a preliminary injunction, and that the injunction was in the public interest.

BSC appeals the decisions regarding claim construction, obviousness, and irreparable harm. None of its arguments support reversal. First, BSC argues noninfringement based on a construction of "lumen" that contradicts the patents, the law, and common sense. The district court thoroughly analyzed the claims, patent specification, and file history as required by *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-17 (Fed. Cir. 2005) (*en banc*) and correctly rejected BSC's invitation to ignore the intrinsic evidence in favor of extrinsic evidence divorced from the patents. A26-30. This Court should similarly find that the hair-width, enclosed, nonfunctional "space" in Guidezilla's rail structure is not a "lumen" as would have been understood by a person of ordinary skill at the time of VSI's invention. This Court should also reject BSC's argument that a lumen present in Guidezilla's collar – not in its rail structure – brings Guidezilla outside the claim limitations, based on BSC's proposed construction of a new claim term, "defining." This Court should decline BSC's invitation to construe a claim term for the first time on appeal. *See Golden Bridge Techn. Inc. v. Nokia, Inc.*, 527 F.3d 1318, 1323-24 (Fed. Cir. 2008). Even if the Court considers the argument, BSC's construction requires a distortion of the claim language and contradicts other intrinsic evidence.

Second, BSC argues that the district court erred in finding that VSI was likely to overcome BSC's obviousness defense. BSC relies primarily on the Adams patent, in combination with any of three other patents – Verbeek, Steinke, and Alt. BSC ignores key limitations in VSI's patents' dependent claims that are not present in any prior art, including those requiring that the proximal opening be able to receive an interventional cardiology device while within the guide catheter lumen. The court also correctly found that, under these circumstances, it was insufficient for BSC to establish merely that the references were within the same technical field, and that BSC failed to provide sufficient evidence of a motivation to combine the references. A34-35. Finally, the court correctly found that multiple secondary considerations – including commercial success, praise by others, and copying – weighed in favor of finding the asserted claims nonobvious. A35. The court's factual findings regarding obviousness had ample support in the record, and the court did not abuse its discretion in finding that VSI was likely to overcome BSC's invalidity challenge at trial.

The Court should also reject BSC's attempt to raise a new invalidity challenge on appeal and to include in the record prior art and other documents not in the district court record. Even if the Court were to consider the Klein patent for the first time on appeal, Klein does not supply the missing elements of the asserted

claims and is no more likely to have been combined with Adams than BSC's originally-cited prior art.

Finally, BSC concedes that, before the injunction took effect, its infringement was causing VSI irreparable harm. BSC asserts, however, that the district court erred when it did not state that VSI's harm was tied to infringement of one specific, novel feature of the claims. BSC's nexus argument relies entirely on the Court's *Apple v. Samsung* decision, which is expressly limited to cases "where the accused product includes many features of which only one (or a small minority) infringe." *Apple*, 695 F.3d at 1374. There is no plausible argument that BSC's infringing Guidezilla catheter – which, as a whole, is an embodiment of VSI's invention – falls within the *Apple* holding. The court did not abuse its discretion when it found that irreparable harm was likely to result from BSC's infringement.

The district court committed no error – factual or legal – supporting a conclusion that it abused its discretion in granting VSI's preliminary injunction motion. VSI respectfully requests that the Order be affirmed in its entirety.

ARGUMENT

BSC cannot show that the court abused its discretion when it preliminarily enjoined BSC from continuing its infringement of VSI's patents. This is not a subtle case of patent infringement; rather, VSI's strong evidence of BSC's blatant

copying and infringement, and the resulting high probability of irreparable harm, present textbook facts satisfying the four-factor preliminary injunction test. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1049 (Fed. Cir. 2010).

I. STANDARD OF REVIEW

In reviewing a court's grant of a preliminary injunction, this Court applies the law of the regional circuit, unless the consideration is specific to patent issues. *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 894 (Fed. Cir. 1998). "A district court has broad discretion in ruling on requests for preliminary injunctions," and therefore, this Court should reverse the grant of preliminary injunctive relief to VSI only if the district court rested its decision on clearly erroneous factual determinations or an error of law, thereby abusing its discretion. *See Kroupa v. Nielsen*, 731 F.3d 813, 818 (8th Cir. 2013); *Rogers Gp., Inc. v. City of Fayetteville, Ark.*, 629 F.3d 784, 786 (8th Cir. 2010). With regard to factors underlying the injunction, the Court reviews claim construction *de novo*, the factual findings underlying obviousness for abuse of discretion, and irreparable harm for abuse of discretion. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1451 (Fed. Cir. 1998); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1379 (Fed. Cir. 2006); *Apple*, 695 F.3d at 1376.

BSC severely understates its burden when it argues that it "need only show that one of the factual premises upon which the district court relied was clearly

erroneous." BSC Br. at 18-19. BSC pulled its "standard" from dicta in a case where the parties' dispute centered on the identity of the inventor. *See New England Braiding Co., Inc. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992). Clearly, the identity of the inventor is "one fact" that might lead to reversal, if incorrect, but that does not mean that every erroneous fact will change the outcome on appeal. The ultimate question on appeal is whether the district court abused its discretion in entering the injunction.

II. THERE WAS NO LEGAL ERROR IN THE DISTRICT COURT'S CLAIM CONSTRUCTION, AND VSI IS LIKELY TO ESTABLISH INFRINGEMENT OF MULTIPLE CLAIMS

The parties asked the district court to construe only one term during preliminary injunction proceedings – the term "lumen" as it appears in the limitation "a substantially rigid portion . . . defining a rail structure without a lumen." The court thoroughly analyzed the construction and concluded that "a person having ordinary skill in the art of cardiac catheterization procedures/interventional cardiology would understand 'lumen' as used in the phrase . . . to mean 'a passageway through which interventional cardiology devices are insertable.'" A29-30. While this Court will review the construction *de novo*, the district court analyzed the claims, specification, and file history as required by *Phillips*, appropriately giving lesser weight to extrinsic evidence. As a result, the

court's claim construction is correct, and VSI is likely to establish that Guidezilla infringes multiple claims of VSI's patents.

1. "Without a Lumen" Applies To The Rail Structure, Not The Collar Or Entire Substantially Rigid Portion

BSC first argues that Guidezilla does not infringe because its substantially rigid portion includes a collar with a lumen. But the claims do *not* require a "substantially rigid portion without a lumen." Instead, they require "a substantially rigid portion proximal of and operably connected to . . . the flexible tip portion and defining a rail structure without a lumen." As the district court correctly concluded, "without a lumen" modifies the *rail structure* in the substantially rigid portion, not the substantially rigid portion as a whole, and not the collar transition operably connecting the substantially rigid portion and the flexible tip. A25. BSC presents no evidence that one of ordinary skill would consider a collar (which by design goes *over* a rail or guidewire) to be a "rail structure."

BSC's argument also cannot be correct, because some of the claims require that the substantially rigid portion have both a rail structure *without* a lumen and a collar *with* a lumen. For example, '032 patent, claim 13 depends from claim 11, which requires "a substantially rigid portion . . . defining a rail structure without a lumen." A71. Claim 13 adds the requirement that the substantially rigid portion include "a partially cylindrical portion defining an opening extending for a distance along a side thereof . . . adapted to receive an interventional cardiology device

passed . . . into the coaxial lumen." *Id.* The "substantially rigid portion" of the device in claim 18, which also depends from claim 11, includes a "full circumference," "hemicylindrical," and "arcuate" portion. *Id.* Similarly, '413 patent, claim 4 requires that its "substantially rigid portion" "comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof." A93. If the collar's lumen is – as BSC urges – part of the rail structure, then it would be impossible to have both a rail structure without a lumen and a collar with a lumen, as required by several dependent claims. "An interpretation of one claim that renders another claim meaningless is disfavored." *Cytologix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1173 (Fed. Cir. 2005). The specification also repeatedly teaches that the substantially rigid portion, which "defines a rail structure without a lumen" can also have a portion that is a full cylinder. A89-91, col. 3:46-61, col. 6:34-40, col. 8:34-44. One of ordinary skill would recognize that, if the device has a collar (cylindrical portion), the collar must have a lumen, or the device would not work.

BSC makes a new argument – that the collar lumen defeats infringement, because the claim term "defining" in "substantially rigid portion . . . defining a rail structure without a lumen" requires that the "rail structure without a lumen" is the *only* structure in the substantially rigid portion. BSC Br. at 21-22. BSC's proposed definition requires the Court to construe the claim term "defining" for the

first time on appeal. BSC did not make the argument in its brief below, so the court did not construe the term in its infringement analysis. BSC has waived this argument. *See Golden Bridge*, 527 F.3d at 1323 (party "cannot simply choose to make its arguments in iterative fashion, raising a new one on appeal after losing on its other at the district court"); *Finnegan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1363 (Fed. Cir. 1999)(*de novo* standard of review does not require Court to consider new arguments; party's argument should not be a "moving target").

BSC also presents no intrinsic or extrinsic evidence supporting its theory that the term "defining" requires that the substantially rigid portion and rail structure be "coextensive." BSC Br. at 21. As outlined above, accepting this argument would improperly eliminate several dependent claims. Moreover, other uses of "defining" in the asserted claims refute BSC's construction. For example, claim 13 requires that the "substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along the side thereof." A71. The side opening in this limitation is not the *only* structure in the partially cylindrical portion merely because it *defines* the opening; the plain claim language requires simply that the opening "extend[] for a distance along" the side of the partially cylindrical portion.

Accordingly, the presence of a lumen through Guidezilla's collar is irrelevant to whether the substantially rigid portion defines a rail structure without

a lumen. The claim language plainly was directed at the absence of a lumen in the device's rail structure, not its collar or anywhere else in the substantially rigid portion.

B. A "Lumen" Requires A Passageway For Medical Devices

The second "lumen" alleged by BSC to defeat infringement is a tiny, nonfunctional, and fully-enclosed space within the hypotube that forms Guidezilla's rail structure. That space can only be a "lumen" if, as BSC suggests, "lumen" in the context of VSI's patents encompasses *any* space or cavity within a tubular structure – no matter how small, and regardless of whether it is open or closed, allows passage of devices, or is functional. BSC Br. at 22-28; A805-06 ¶ 6. The district court correctly construed the term to mean "a passageway through which interventional cardiology devices are insertable," finding the intrinsic and extrinsic evidence consistent with VSI's construction.

1. The Intrinsic Evidence Supports The District Court's Construction

The district court's construction is strongly supported by the intrinsic evidence. A242-45. The asserted claims expressly use "lumen" to reference a space that allows an interventional cardiology device to pass, to reach the artery. Claim 1 of the '032 patent recites:

- "the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery"

- "a flexible tip portion defining a tubular structure . . . defining a coaxial lumen [with the guide catheter] having a cross-sectional inner diameter through which interventional cardiology devices are insertable"

A70 (emphasis added). The term "lumen" is used in this way more than thirty times in the claims of the '032 patent. Indeed, *all* independent claims of the patents contain this same type of definitional language. For example, claim 1 of the '413 patent recites, "advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery." A93.

The common specification of VSI's patents also consistently uses "lumen" to refer to a passage through which interventional cardiology devices can pass, to reach the arterial site.

> The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

A52 (Abstract) (emphasis added). The specification refers to the "lumen of the artery" (1:24-25), the "lumen of the guide catheter" (1:35), the "lumen of [the] coaxial guide catheter" (9:59, 9:62), and a "lumen through which a guidewire may be passed" (1:4). A66-70. *See also, e.g.*, A66-68, col. 1:32-36, col. 4:2-4, 5-7, col. 6:60-61.

Consistent use of the term "lumen" in this manner throughout the claims and specification strongly implies that the inventors meant to give "lumen" the same meaning in the limitation at issue. *See AstraZeneca LP*, 633 F.3d at 1052 (patentees may define terms by implication, by using claim terms in a manner consistent with a single meaning); *see also Scimed Life Sys., Inc. v. Advanced Cardiovascular Sys.*, 242 F.3d 1337, 1344 (Fed. Cir. 2001). It also indicates that one of ordinary skill would have understood lumen, in the context of VSI's patents, to mean a passageway through which interventional cardiology devices are insertable.

The patents' specification also teaches – three different times – a preferred embodiment of the patents' claims using a hypotube to form the device's rail structure, as long as the hypotube does not form a passageway for the delivery of devices. A68, col. 6:35-37 ("Rigid portion 20 may be formed from a hypotube or a section of stainless steel or Nitinol tubing."); A67, col. 3:47-48; A69, col. 7:24-25. A claim interpretation that excludes a preferred embodiment, like BSC proposes here, "is rarely, if ever, correct." *On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1138 (Fed. Cir. 2004) (internal citation omitted). After reading the specification, no person of ordinary skill would believe that the mere use of a hypotube to form the rail, with its hair-width "cavity," constitutes a lumen.

That the patents use "lumen" to refer to a passage through which interventional cardiology devices can reach an arterial lesion is not surprising – the purpose of VSI's patented guide extension is to facilitate the treatment of arterial lesions. The claims recite a lumen in the flexible tip portion, because the purpose of the tip is to allow passage, but recite a rail structure without a lumen, because the purpose of that portion is *not* to allow passage, but instead to push the flexible tip into place, and then to allow instruments to travel *next to* the rigid portion, not through it. A66, col. 2:53-56 (invention is a "coaxial guide catheter that is deliverable through standard guide catheters by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter").

BSC cited *no* intrinsic evidence in its district court brief. A703. Now, BSC makes an entirely new argument based on intrinsic evidence – that when the inventors sought to denote an open passageway, they "consistently and expressly described the 'lumen' as 'continuous,'" thereby suggesting that the inventors' failure to use "continuous" to describe the lack of a lumen in the rail structure means that it need not be open to allow devices to pass through. BSC Br. at 24. Again, BSC asks this Court to construe a new claim term, without the benefit of either intrinsic or extrinsic evidence. One could imagine a "lumen" that is not "continuous" (*e.g.*, an interrupted tube) that still allows devices to pass and functions as a lumen.

Even setting aside the meaning of "continuous," BSC's underlying premise – that the patent never refers to an open passageway without using the term "continuous" – is simply wrong. The patents contain numerous "lumen" references that are open passageways but do not use the term "continuous." *See*, *e.g.*, A71, claim 11 (requiring "a flexible tip portion . . . defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable"); A70, col. 9:59-63 (describing a stent or balloon being "inserted through the lumen of coaxial guide catheter 12 which remains inside the guide catheter"). Instead, the VSI patents use the term "continuous" only to modify the lumen *of the guide catheter*. This means that the guide catheter is one continuous segment, as opposed to one lumen extended by another.

BSC is also wrong that the prosecution history supports its construction. BSC Br. at 26 n.5. Contrary to BSC's assertion, the examiner rejected VSI's claims in view of prior art disclosing "a tubular structure . . . [with a] lumen through which cardiology devices are insertable" and noted that *nothing* in Solar precludes a device large enough to receive an interventional cardiology device. A1208; A1214. If relevant at all, the statements support VSI's construction.

2. The Extrinsic Evidence Also Supports The District Court's Construction

The extrinsic evidence also supports the district court's construction. "Lumen," as used in the field of interventional cardiology catheters and by BSC

itself, refers to a passageway. Industry literature about cardiac catheters consistently uses "lumen" to refer to the interior of a tubular structure, open at both ends to allow the passage of medical devices and contrast medium. *E.g.*, A578 ("guiding catheters must have a lumen" of a certain size to "allow passage of therapeutic instruments"); A562 ("guidewire passed through the balloon catheter lumen"); A572 ("It is possible to inject fluids via a guide wire lumen running the entire length of the dilation catheter."); A592-93; A597-98. BSC's own Adams patent and numerous BSC documents use "lumen" to refer to the interior of a tube through which something can pass. *See, e.g.*, A750, col. 7:4-5; A602-11; A1228. In a device context, "lumen" is "the bore of a hollow needle, catheter, etc." A556; *see also* A558.[4]

In advancing a definition of "lumen" that covers any space or cavity within a tubular structure, regardless of whether it allows passage of devices, BSC violates the most basic claim construction principles, ignoring intrinsic evidence in favor of various dictionary definitions, the lawyer-supplied opinion of its "expert" Vrba, and a construction of "lumen" from a court decision relating to a different patent. BSC Br. at 23-28; A702-05. The district court correctly rejected the arguments.

[4] The district court discounted BSC's internal documents, because they were not developed "at the time of the invention." A28 n.7. However, BSC provided no evidence that its internal understanding of "lumen" changed over the past six or seven years, and the documents merely confirm what the intrinsic evidence already shows.

First, BSC argues that the district court erred, because it did not adopt the "construction" of "lumen" in a 16-year old decision of this Court, *Howes v. Med. Components, Inc*., 814 F.2d 638 (Fed. Cir. 1987). This Court cautions against determining the meaning of a claim term based on an unrelated patent. *See Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1318 (Fed. Cir. 2005). This is true even when the patents are in similar fields. *See, e.g., Monsanto Co. v. Bayer Bioscience N.V.*, 363 F.3d 1235, 1245-46 (Fed. Cir. 2004).

At most, the decision in *Howes* is relevant only as nonbinding extrinsic evidence, which "may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification or file history." *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1269 (Fed. Cir. 2001). Elevating the *Howes* decision above intrinsic evidence would be particularly inappropriate here, where *Howes* construed a patent filed thirty years before VSI's patents.

Regardless of its persuasive value, *Howes* does not actually say what BSC argues. The *Howes* Court was construing the terms "joined" and "freely," not "lumen," because the patent at issue expressly defined "lumen" as "individual tubes or elongated ***passageways*** formed in a body." *Howes*, 814 F.3d at 644 (emphasis added). While *Howes* was concerned with the passage of fluid, rather than devices, a characteristic of all the "lumens" in *Howes* was that they served as

passageways, even if a device was sometimes added to the lumen to block that flow or passage. The court correctly discounted the persuasive value of *Howes* in construing "lumen" in the context of VSI's patents.

Second, BSC's dictionary definitions are ambiguous at best; blood vessels, ducts, and intestines, for example, are open on both ends so matter can pass through. A771; A775; A779; A783; A787. More fundamentally, by starting with extrinsic evidence divorced from the patents, BSC follows a methodology rejected by this Court, because it

> placed too much reliance on extrinsic sources such as dictionaries . . . and too little on intrinsic sources, in particular the specification and prosecution history. . . . [H]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification.

Phillips, 415 F.3d at 1320-21; *see also Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

Finally, BSC's expert adds nothing to its argument – Vrba did not even perform his own analysis. BSC's lawyers prepared BSC's proposed definition. A1185. After testifying that he had reviewed only the patent claims, and not their specifications, A1166-68, Vrba later clarified that he had read other parts but not in one sitting. A1186-87. Vrba's sole investigation regarding the meaning of "lumen" was one Google search revealing a Wikipedia definition related to the gut.

A1184-85. Vrba identified no device and no patents, articles, or other extrinsic evidence discussing a device, with a "lumen" having closed ends.

No document – intrinsic or extrinsic – references any hair-width, closed, nonfunctional space as a lumen in the context of cardiac catheters. A person of ordinary skill – having read in the patent that the rail structure provides pushability and can be formed from a hypotube – would never conclude that "any" space creates a lumen. Taken to the extreme, "any" space could encompass an air bubble one micron across – an absurd result. If nothing can be delivered through a cavity in a solid object, that open space may be a volume or a void, but it clearly is not a "lumen."

The district court's construction of "rail structure without a lumen" should be affirmed.

C. VSI Is Likely To Establish BSC's Infringement Of Multiple Claims

Guidezilla has a rail structure "without a lumen," and therefore infringes '032 patent claims 3, 4, and 13; '413 patent claims 4, 9, and 10; and '850 patent claims 3, 4, and 14. BSC's expert and documents establish that its pushrod hypotube is closed on both ends. A1183-84; A1255. The alleged "cavity" within the hypotube is the width of a hair. A1103-04 ¶ 44. No medical device can pass through it. A240-41 ¶ 90. BSC admits that its hypotube does not have **XXXX XXXX**" A1228. VSI submitted evidence establishing BSC's infringement of the

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remaining claim limitations, and BSC concedes as much. Accordingly, the district court did not abuse its discretion when it determined that VSI was likely to succeed on the merits of its infringement claims.

III. THE DISTRICT COURT CORRECTLY FOUND THAT BSC WAS NOT LIKELY TO ESTABLISH THAT THE ASSERTED CLAIMS WERE OBVIOUS

A. Standard Of Review

BSC incorrectly urges this Court to conduct a *de novo* review of the district court's obviousness determination. BSC Br. at 18. However, this Court should review the court's obviousness analysis "in light of the deferential standard [this Court] appl[ies] in reviewing grants or denials of preliminary injunctions." *Sanofi-Synthelabo*, 470 F.3d at 1375.

"Obviousness is a question of law based on underlying findings of fact." *In re Kubin*, 561 F.3d 1351, 1355 (Fed. Cir. 2009). Factual inquiries relevant to obviousness include: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims, (3) the level of ordinary skill in the art, and (4) secondary considerations of nonobviousness. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007). Additionally, the presence or absence of a motivation to combine references "is a pure question of fact." *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). While the Court will review the ultimate legal question of invalidity *de novo*, the district court's findings with respect to these

underlying factual questions should be reversed only if they were clearly erroneous. *See Sanofi-Synthelabo*, 470 F.3d at 1374; *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 929 (Fed. Cir. 2012).

Finally, like the district court, this Court must consider the invalidity question "mindful that a patent is presumed valid, and this presumption exists at every stage of the litigation," including during preliminary injunction proceedings. *Sanofi-Synthelabo*, 470 F.3d at 1375; *see also Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009). It was BSC's burden to come forward with evidence of invalidity, just as it would be at trial. *See Titan Tire*, 566 F.3d at 1377. The ultimate question is whether BSC raised a substantial question of validity, such that "it is more likely than not that [BSC] will be able to prove at trial, by clear and convincing evidence, that the patent is invalid." *Id.* at 1379.

B. The District Court Correctly Found That VSI Was Likely To Overcome BSC's Obviousness Defense Based On Adams/Verbeek/Alt/Stein

BSC relied primarily on the Adams patent as the basis for its contention that the asserted claims are obvious. However, BSC and its expert Vrba concede that Adams does not disclose every limitation of the asserted claims, including the novel transition collar. A1169. Indeed, Adams does not disclose anything similar to the collar limitations – instead, Adams' pushrod is connected directly to the flexible tube. Root explained in detail why VSI's patented collar made GuideLiner

a superior device to the one described in Adams. A1083-93 ¶¶ 2-22. VSI's collar transition provides superior pushability, because it translates the force from the narrow pushrod to the full circumference of the flexible tubular portion, thus making GuideLiner easier to advance. The collar also provides a smoother transition from pushrod to flexible tube than Adams, so that GuideLiner is "adapted to receive" a stent or other device while inside the guide catheter, reducing the risk that the stent will catch or dislodge. A1091-93 ¶¶ 18-22. The Adams patent itself admits the device has problems with lack of pushability. A747, col. 2:58-62; A753, col. 14:58-62; A754, col. 16:16-28. The collar's advantages were critical to GuideLiner's success, A1091-93 ¶¶ 18-22; and Adams's defects may explain why Guidezilla does not follow Adams' teachings, but rather copies GuideLiner's collar.

In its opposition below, BSC relied on Verbeek, Steinke, and Alt to fill in the collar elements it conceded were missing from Adams. A719-20; A950-56. The court rejected BSC's arguments, finding that structures found in Verbeek, Steinke, and Alt were not adapted for use or used for the same function as the collar in VSI's patents; that VSI presented evidence that using the Verbeek/Steinke/Alt structures with Adams to perform the function disclosed in VSI's patents would be impossible; and that BSC provided no motivation to combine Adams with Alt/Steinke/Verbeek. A34-35. BSC has not shown that the

district court's findings were factually or legally erroneous, and the Court should affirm the finding that Adams, when combined with Verbeek, Steinke, or Alt, is not likely to render the asserted claims obvious.

1. Verbeek/Steinke/Alt Do Not Disclose All Of The Missing Limitations Of The Asserted Claims

A patent is not obvious if one of its limitations was not taught in the prior art. *See Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1308-09 (Fed. Cir. 2010); *Vizio, Inc. v. Int'l Trade Comm'n*, 605 F.3d 1330, 1343 (Fed. Cir. 2010). The district court correctly found that, because the combination of Adams with Verbeek, Steinke, or Alt does not teach all of the limitations of the claims, BSC was not likely to establish that the claims are obvious. A34.

The independent claims of VSI's patents generally claim the flexible tubular portion and the substantially rigid portion of the invention. The dependent claims supporting the injunction add limitations covering the transitional collar shapes and the collar's ability to receive interventional devices while inside the guide catheter. BSC attempts to narrow the nine dependent claims as "addressed to the shape of the proximal opening of the flexible tube – namely, a tube skived or cut at an angle," openings which BSC claims were "routinely employed" and "a common design choice" in rapid exchange catheters by 2004. BSC Br. at 28-29, 33. BSC cites Verbeek, Steinke, and Alt as examples of such "skived" openings. *See* BSC Br. at 31-33.

As the district court recognized, BSC's obviousness challenge is based on a mischaracterization of the claim limitations. The collar limitations relate both to the shape of the collar opening, claiming it as a "proximal side opening" or an opening with a "full circumference portion" and a "partially cylindrical portion," *and* to the collar's ability "*to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter*." *See, e.g.*, A70-71 (claims 3, 4, 13); A114 (claims 3, 4, 14); A93 (claims 4, 9, 10).

Alt, Steinke, and Verbeek do not disclose the additional limitations of the dependent claims that were the basis for the injunction. As the district court correctly found, Alt/Steinke/Verbeek disclose nothing more than sloped exit ports on balloon catheters, all of which are quite different in design, function and utility from VSI's invention. A34. The prior art ports are configured to allow a guidewire to *exit* a balloon catheter, not as an entrance for anything. A1174; A1181. Exits and entries are fundamentally different, and exit ports do not teach entry points, even if both may be sloped. *Cf. St. Jude Med., Inc. v. Access Closure, Inc.*, 729 F.3d 1369, 1381 (Fed. Cir. 2013) (prior art did not disclose use of balloon to position plug to stop bleeding; prior art taught only use of balloon directly to control bleeding).

The exit ports in Verbeek, Alt, and Steinke could not possibly be used to insert a device when the balloon catheter is inside a guide catheter, which is the purpose of VSI's collar. As Vrba admits, the opening of the guidewire exit port is too small to accommodate devices such as stents or balloon catheters. A1174; A78-79; A1182-83. Even if a device were small enough, Vrba concedes it would be impossible to insert it into a guidewire exit port when the port is inside a guide catheter. *Id.* Using Verbeek's exit as an entrance would be akin to threading a needle at the end of a 100cm tube in the dark; the Alt and Steinke notches would add even more difficulty, requiring a sharp turn to enter the eye of the needle. *See* A1100-01 ¶ 38.

BSC relies on a paragraph in its expert's declaration, wherein Vrba argues that, "[b]y 2004, sloped or angled openings to lumens were well known to persons of ordinary skill in the art of rapid exchange catheters." BSC Br. at 30. But Vrba admits it would be impossible to do so in Verbeek, Steinke, or Alt, and cites no example where such an opening was used to insert a device when the catheter was inside a guide catheter, as claimed in VSI's patents. *See* A1174; A1178-79; A1182-83.

Thus, even in combination, BSC's prior art does not disclose all elements of the dependent claims supporting the injunction. BSC falls far short of establishing that the district court's findings were clearly erroneous.

2. BSC Presented No Evidence Establishing A Motivation To Combine Adams With Verbeek/Steinke/Alt

Even if BSC could identify the missing elements in the prior art, it still did not make even a minimal showing of obviousness. "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418 (2007); *see also Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361 (Fed. Cir. 2011). BSC was required to articulate why one of ordinary skill would have been motivated to combine the prior art teachings to achieve the claimed invention, and why the person of ordinary skill would have reasonably expected success in doing so. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1369-70 (Fed. Cir. 2012). "This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered . . . ." *KSR*, 550 U.S. at 418.

The district court correctly found that BSC did not identify adequate motivation to combine Adams with Alt, Steinke, or Verbeek. A35. Vrba's say-so is BSC's sole support for a motivation to combine the references. But Vrba appears to be little more than a mouthpiece for BSC's lawyers and made no real analysis of the issue. BSC's lawyers selected the references for him, presumably because each depicts a slanted opening in a catheter. Vrba read only the portions of the patents to which he was directed. A1161-63; A1170. The district court did not abuse its discretion in finding Vrba's vague and conclusory testimony

insufficient to support the motivation to combine necessary to render the asserted claims obvious. *See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (expert testimony too vague to support a motivation to combine); *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1373-74 (Fed. Cir. 2008) (affirming preclusion of conclusory expert testimony regarding motivation to combine).

BSC also asserts that the district court erred, because it failed to find a motivation to combine based on the mere fact that the prior art patents were "within the same 'field of endeavor.'" BSC Br. at 34 (*citing KSR*, 550 U.S. at 417). Essentially, BSC argues that a person of ordinary skill would have been motivated to combine the patents simply because "all address the delivery of devices for interventional cardiology and treatment of vascular disease." BSC Br. at 35. This is incorrect; BSC relies on the interventional cardiology devices themselves, not devices constructed *for their delivery*. Regardless, relating to the same general field of technology cannot be enough to provide a motivation to combine them in the particular way claimed in VSI's patents. Prior art – by definition – is either in "the field of the inventor's endeavor" or "reasonably pertinent to the particular problem with which the inventor was involved." *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1339 (Fed. Cir. 2005).

BSC's obviousness defense is an extreme case of using hindsight to try to recreate a patented invention. BSC's lawyers improperly started with the patented invention and then reached back to the prior art seeking out any reference that touched on the individual elements comprising VSI's invention. *See Kinetic Concepts*, 688 F.3d at 1368. There is no reason why one of ordinary skill would have thought to take a sloped *exit* port from Alt/Steinke/Verbeek, enlarge and convert that exit port into an entrance collar, modify it so it meets the limitations of all nine dependent claims, and use it to replace the perpendicular direct connection between the pushrod and flexible tube taught in Adams. No prior art describes VSI's collar, or even any benefit of a sloped exit port to improve the entrance of a device into the lumen, to reduce any obstruction at the entrance of the flexible tubular portion, or to improve the catheter's pushability – the benefits of VSI's collar invention. "When a field is unreduced by direction of the prior art, and when prior art gives no indication of what parameters were critical or no direction as to which of many possible choices is likely to be successful, an invention is not obvious to try." *See Unigene Labs.*, 655 F.3d at 1361 (internal quotation omitted).

The Adams inventors knew their device had problems, but were unaware of the cause or solution. Those problems remained until VSI solved them. A1101 ¶ 39. Adams taught that the tube's excessive flexibility caused the device's pushability problems, A747, col. 2:58-62; A753, col. 14:58-62; thus, one of

ordinary skill would not appreciate or try to solve the problem by developing a new collar. Indeed, Adams' focus on flexibility would lead one of ordinary skill in the wrong direction. The strongest practical evidence of that fact is that BSC acquired the Adams patent many years ago, but failed to commercialize Guidezilla until VSI solved the problem years later. At that point, BSC simply copied VSI's solution.

3. The District Court Correctly Found That Secondary Considerations Weigh In Favor Of Finding The Asserted Claims Were Not Obvious

Objective indicia of nonobviousness "are powerful tools for courts faced with the difficult task of avoiding subconscious reliance on hindsight." *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012) (objective criteria help turn back the clock; incremental steps in retrospect may seem deceptively simple, particularly in hindsight). The district court correctly found that VSI presented "evidence of multiple objective indicators of nonobviousness including commercial success, praise by others, and copying" by BSC. A35 (citing A218 ¶ 39; A219-22 ¶ 44; A230-36 ¶¶ 68-79; A334-414). BSC does not dispute the findings of commercial success and praise. Instead, BSC argues that the court erred in considering the evidence, because there was no "analysis of whether and how the claimed side openings contributed to that success or praise." BSC Br. at 42.

BSC's nexus attack on the district court's opinion is wrong. First, Root explained in detail how GuideLiner's collar is critical to the success of the product. A1091-93 ¶¶ 18-22.

Second, BSC concedes that GuideLiner is an embodiment of and coextensive with the patent claims at issue. BSC Br. at 44 n.7; *see also* A211-17 ¶¶ 21-36; A261-328. There is therefore a presumption of a nexus between GuideLiner's commercial success and the claimed invention. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 1372-73 (Fed. Cir. 2013); *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997).

BSC relegates its only attempt to rebut that presumption to a footnote. There, BSC argues that the presumption may be overcome if the feature creating commercial success was known in the prior art. BSC Br. at 44 n.7 (*citing Ormco Corp. v. Algin Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006)). However, as explained in detail above, BSC has not established that the limitations pertaining to GuideLiner's collar were previously disclosed. The difference between the claimed entrance opening in VSI's patents, and the exit ports in Alt/Steinke/Verbeek have more than a minor technical significance; the difference in functionality alone is central to the success of the invention. No prior art discloses an entrance port designed to receive devices while inside the guide catheter.

With respect to copying, BSC provided no evidence to dispute that it copied GuideLiner and its collar. *See* A13 (BSC does not dispute that Guidezilla is almost an exact copy of GuideLiner). Regardless, the copying is obvious, and substantial evidence supports the district court's finding. *See* A230-36 ¶¶ 69-79; A523-32; A227-29. BSC's Guidezilla files contain **XXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXX**. A1113 ¶ 2; A1287-88. Indeed, if Guidezilla was in fact modeled on the Adams patent, Guidezilla would have no collar at all, A738; A742, and would likely have been developed and commercialized by BSC at the time of the Adams invention.

C. BSC's Late Addition Of Klein Does Not Render The Asserted Claims Obvious

1. BSC Waived Any Argument Relying On Klein, And Klein Should Be Stricken From The Record On Appeal

BSC did not make the Adams-Klein argument in its district court brief, and Vrba offered no testimony about Klein. BSC's lawyers first mentioned Klein during oral argument, giving VSI no opportunity to analyze or offer expert testimony. Neither Klein nor the file history excerpts mentioning Klein are part of the district court record.

BSC waived the Adams-Klein obviousness argument and this Court should not consider it. "It is the general rule . . . that a federal appellate court does not consider an issue not passed upon below." *Golden Bridge*, 527 F.3d at 1322

(refusing to consider prior art argument); *see also Rentrop v. Spectranetics Corp.*, 550 F.3d 1112, 1117 (Fed. Cir. 2008).

BSC did not preserve the issue by referencing Klein at the hearing and in its request for reconsideration. BSC Br. at 38. Courts in the District of Minnesota have found waiver when an issue is first raised at oral argument. *E.g.*, *Breathablebaby, LLC v. Crown Crafts, Inc.*, 2013 WL 5230724, *5 n.3 (D. Minn. Sept. 17, 2013); *Donaldson Co., Inc. v. Baldwin Filters, Inc.*, 2011 WL 2183179, *8-9 (D. Minn. June 6, 2011). *Cf. Emenaker v. Peake*, 551 F.3d 1332, 1339 (Fed. Cir. 2000) (argument presented for the first time in lower court reply brief and not addressed in lower court opinion deemed waived). Nor did BSC preserve the issue by making the argument in its request for reconsideration. *Bluebonnet Sav. Bank, F.S.B. v. United States*, 466 F.3d 1349, 1361 (Fed. Cir. 2006) (argument first made in reconsideration motion comes too late and is deemed waived).

The waiver rule exists for good reason. By waiting until oral argument, BSC left the district court to determine the scope and content of technical prior art based solely on lawyer argument, which the court appropriately declined to do, and deprived VSI of any meaningful opportunity to respond. As a result, this Court has no district court factual findings or analysis to review. *See Golden Bridge*, 527 F.3d at 1323 ("We decline to determine what a prior art reference discloses, a fact finding, in the first instance on appeal."); *Fresenius USA, Inc. v. Baxter Int'l, Inc.*,

582 F.3d 1288, 1296 (Fed. Cir. 2009) (anticipation argument should have been presented to district court).

Moreover, Klein and file history excerpts mentioning Klein are not part of the record on appeal. *See* Fed. R. App. P. 10(a); *Sky Techs. LLC v. SAP AG*, 576 F.3d 1374, 1377 n.4 (Fed. Cir. 2009) (refusing to consider document not in the district court record); *Gen. Motors Corp. v. Harry Brown's, LLC*, 563 F.3d 312, 318 n.3 (8th Cir. 2009) (striking evidence not presented to district court). No rule or case law supports BSC's argument that Klein and the file history should be considered now simply because they *could have been* "part of the intrinsic evidence." BSC Br. at 38. *See Am. Standard, Inc. v. Pfizer, Inc.*, 828 F.2d 734, 746 (Fed. Cir. 1987) (striking file history submitted for the first time on appeal).

BSC's "time constraints" argument is not correct. BSC Br. at 39 n.6 (*citing New England Braiding*, 970 F.2d at 882-83). Some preliminary injunction motions may be decided under severe time pressures, but BSC had nearly two months between notice of VSI's preliminary injunction motion and its opposition brief; another six weeks before the hearing; and three more months before the court's order. BSC's attempt to blame VSI should also be rejected. BSC Br. at 38. VSI addressed Adams, Verbeek, Alt, and Steinke at its first opportunity – when BSC first raised them in its opposition brief. Had BSC identified any obviousness argument whatsoever in response to VSI's prior correspondence or during the

parties' prior discussions,[5] VSI would have addressed it in its opening brief. Regardless, BSC never asked for leave to file a surreply or present evidence or written arguments regarding Klein after oral argument. BSC's submission of Klein and the file history references in the appeal appendix was improper, and the evidence should be stricken from the record. Fed. Cir. R. 27(e).

2. Klein Is Missing Key Elements Of The Asserted Claims And There Is No Evidence Establishing A Motivation To Combine

Even if this Court were to consider the new Adams-Klein combination, the district court's order should be affirmed. Based entirely on lawyer argument, BSC now claims that Klein cures the deficiencies of Alt, Verbeek and Steinke, because Klein's angled opening is an entry port that remains within the guide catheter. BSC Br. at 37. But BSC presents no *evidence* to support its lawyers' reading of the prior art. "Unsubstantiated attorney argument regarding the meaning of technical evidence is no substitute for competent, substantiated expert testimony." *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1068 (Fed. Cir. 2005).

More importantly, BSC's argument is factually wrong. The Klein device combines a balloon and a stent mounted on the outside of a catheter, but teaches nothing about guide catheter extension or delivery of a device through the lumen of

[5] BSC violated the district court's "meet and confer" requirements when it failed to disclose the defense. D. Minn. L.R. 7.1(a). *See also* A1113-14 ¶¶ 3-9; A552-54.

a guide catheter. Klein also does not teach use of an angled proximal opening for the *entry* of anything while within the lumen of the guide catheter.

BSC relies on Klein's Figure 28 to argue that "a device such as a balloon catheter (not only a guide wire) ***enters*** the catheter lumen through the proximal port [of the Klein device], while it is inside the guide catheter." BSC Br. at 37 (emphasis in original). But this is incorrect. Klein explains the method shown in Figure 28 in some detail. A2453-54, col. 14:32-15:18.[6] While the Klein device and balloon catheter are both *outside the patient's body* (not within the guide catheter), the balloon catheter can be inserted into the Klein device through the proximal opening of the device's tubular portion. The balloon catheter is pushed all the way through the device and exits the tubular portion's distal tip (Figure 29). A2443. That entire assembly is only then inserted into and through the guide catheter. The balloon catheter is positioned and used to expand the lesion (Figure 30). *Id.* Then, the Klein device is held in place while the now-deflated balloon is *pulled backwards* into the Klein tubular portion. A2453. Inside the guide catheter, the balloon enters the tubular portion's *distal* tip opening (which is not slanted, but perpendicular to the device's longitudinal axis) (Figure 32), A2444, and then is re-inflated to place the stent at the lesion. The balloon catheter never enters the

[6] As noted in its motion to strike, VSI objects to any consideration of Klein on appeal.

tubular portion's proximal port while inside the guide catheter lumen, as required by the dependent collar claims of VSI's patents.

To facilitate entry of the balloon catheter into the device's perpendicular *distal* tip opening, Klein teaches two solutions that are nothing like the collar in VSI's patents: first, making the tubular portion's lateral distal tip soft and expansible, A2452, col. 11:44-47, and second, positioning a cone on the balloon catheter's proximal end to help the balloon catheter enter Klein's perpendicular distal opening, A2453, col. 14:50-52. Thus, far from disclosing VSI's invention, Klein teaches away from the solution offered by VSI's collar.

Accordingly, even with the late addition of Klein, BSC has not demonstrated a prior art combination that discloses the elements of VSI's collar claims.[7] And, as with Verbeek/Steinke/Alt, BSC's Klein argument is also pure lawyer hindsight. BSC has not shown any motivation to combine the opening in Klein with the Adams patent to create the combination of flexible tip portion, innovative collar, and substantially rigid portion claimed in VSI's patents.

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[7] BSC argues that the file history shows a rejection of the dependent collar claims based on Klein and other prior art. BSC Br. at 37. But this does not bear on novelty. In any event, VSI did not acquiesce to the examiner's rejection on this point, and the claims were granted after the addition of "defining a rail structure without a lumen." "An applicant's silence in response to an examiner's characterization of a claim does not reflect the applicant's clear and unmistakable acquiescence to that characterization if the claim is eventually allowed on grounds unrelated to the examiner's unrebutted characterization." *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1373-74 (Fed. Cir. 2003).

IV. THE DISTRICT COURT CORRECTLY FOUND THAT VSI HAD ESTABLISHED IRREPARABLE HARM CAUSED BY BSC'S INFRINGEMENT

When a large company like BSC combines a nearly identical product with its greater resources to compete against a smaller company's patented flagship product, irreparable harm inevitably will result. VSI submitted to the district court a detailed evaluation of likely harm, supported by past examples, by BSC's own actions in the marketplace, and by legal precedent. A246-54 ¶¶ 107-30. The court found *actual evidence* of price erosion and lost sales to BSC, that the patented technology is "central to" VSI's business, and that "the harm to [VSI] in the absence of an injunction is likely to be greater than that caused to [BSC] by an injunction." A37-39. Those findings are entitled to deference, and the conclusion that VSI established irreparable harm as a result of BSC's infringement should be affirmed absent a finding that the district court abused its discretion. *See Medicine Shoppe Int'l, Inc. v. S.B.S. Pill Dr., Inc.*, 336 F.3d 801, 805 (8th Cir. 2003); *Apple*, 695 F.3d at 1376.[8]

BSC concedes that its infringing Guidezilla sales were causing substantial irreparable harm to VSI before the injunction took effect. BSC asserts only that VSI must show that its harm is caused by BSC's infringement of some specific,

[8] BSC is wrong that a finding of irreparable harm is reviewed "without deference." BSC Br. at 18 (citing *Apple*, 695 F.3d at 1374). *Apple* repeatedly states that the Court's review of the district court's finding of irreparable harm was for abuse of discretion. *E.g.*, *id.* at 1374, 1376, 1377.

novel feature of the patents, and that the court erred because it did not explicitly discuss whether the harm flowed from Guidezilla's "allegedly infringing side opening." BSC Br. at 46-47 (*citing Apple*, 695 F.3d at 1374-75, 1377).

Apple does not require a patentee to show that its irreparable harm flows from a specific limitation in the infringed claim. *Apple* stands only for the unremarkable proposition that irreparable harm must have a sufficiently strong causal nexus with the alleged *infringement*. *Apple*, 695 F.3d at 1374. *Apple*'s contribution to that law – that products with many features, some patented and some not, must be carefully examined for nexus – was expressly tied to the particular nature of the infringing smartphone devices and their myriad features. *Id.* ("[I]n cases such as this – where the accused product includes many features of which only one (or a small minority) infringe – a finding that the patentee will be at risk of irreparable harm does not alone justify injunctive relief."). *See also Lifescan, Inc. v. Shasta Techs., LLC*, 933 F. Supp. 2d 1243, 1262 (N.D. Cal. 2013), *rev'd on other grounds*, 734 F.3d 1361 (Fed. Cir. 2013) (unlike the *Apple* smartphones, infringing product "embod[ied] a substantial part of the patented features and not much else").

Here, GuideLiner *is* the patented invention, and Guidezilla is a nearly exact copy of it. Guidezilla as a whole is alleged to infringe the asserted claims. Contrary to BSC's assertion that the dependent claims are "directed to one narrow

feature of the accused product," BSC Br. at 42, the dependent claims, together with the independent claims from which they depend, cover the invention as a whole – a guide extension catheter with VSI's inventive combination of flexible tip portion, pushrod, and collar. VSI submitted substantial evidence of accolades and studies establishing the invention's clinical benefits, as well as testimony establishing that those benefits – copied by BSC – and VSI's growing product sales are tied to GuideLiner's patented design. A211-17 ¶¶ 21-36; A218-22 ¶¶ 39-45; A329-51; A1309-10; A1084 ¶ 5; A1091-93 ¶¶ 18-22. This fact is further demonstrated by the lack of competitive devices on the market, with the only recent exception being BSC's copycat Guidezilla device. A246-47 ¶ 107.

V. THE COURT SHOULD STRIKE EVIDENCE THAT IS NOT PART OF THE RECORD ON APPEAL

Pursuant to Local Rule 27(e), VSI moves to strike the documents listed below. Over VSI's objection, BSC included in the parties' Joint Appendix over 1,400 pages that are not part of the district court record.[9] *See* Fed. R. App. P. 10(a); Fed. R. App. P. 30(a).

- **Documents not in district court record (1,002 pages):**
  1. '032 patent prosecution history (A1333-1785)
  2. '413 patent prosecution history (A1786-1976)

[9] Because BSC has not yet filed its reply brief, VSI cannot provide the Court with a list of specific documents that BSC plans to file as part of the final appendix.

3. '850 patent prosecution history (A1977-2095)

4. BSC's presentation demonstratives from August 27, 2013 Preliminary Injunction Hearing (A2184-2325)10

5. Deposition Transcript of Howard Root, June 27, 2013 (A2359-2407)

6. Pub. No. U.S. 2003/01955P46 A1 (Solar) (A2408-2423)

7. Klein patent (A2424-2455)

- **Documents filed with the district court after entry of preliminary injunction order (18 pages):**

8. VSI Notice of Posting Bond (A1312-1318)

9. BSC Letter Requesting Permission to File Motion to Reconsider (A1319-1320)

10. Order Staying Preliminary Injunction Order (A1321-1322)

11. VSI Letter Opposing BSC's Request to File Motion to Reconsider (A1323-1324)

12. Order Denying Request for Permission to File Motion to Reconsider (A1325-1329)

- **Documents previously filed in this appeal (406 pages):**

13. Appellant's Motion for an Interim Stay and Stay Pending Appeal and Addenda A-D (A2456-2480)

14. Declaration of Seth Heller In Support of Appellant's Motion for an Interim Stay and Stay Pending Appeal, with Exhibits 1-24 (A2535-2915).

[10] BSC showed portions of this slideshow as a demonstrative, but did not offer the document as an exhibit or otherwise enter the slideshow into the record.

CONCLUSION

The district court did not abuse its discretion in enjoining BSC from making, using, offering to sell, or selling its Guidezilla product, and from contributing to or inducing others to infringe VSI's patents. VSI respectfully requests that this Court affirm the district court's order.

Respectfully submitted,

DORSEY & WHITNEY LLP

Dated: January 29, 2014

By /s/ Heather D. Redmond
J. Thomas Vitt
Heather D. Redmond
50 South Sixth Street, Suite 1500
Minneapolis, MN 55402-1498
Telephone: (612) 340-2600

Attorneys for Plaintiff-Appellee Vascular Solutions, Inc.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 27(d) and 32(a)(7)(B). The brief contains 13,927 words, excluding the parts of the brief exempted by Federal Rules of Appellate Procedure 32(a)(7)(B)(iii).

/s/ Heather D. Redmond
Attorney for Plaintiff-Appellee

CERTIFICATE OF SERVICE

I hereby certify that on January 29, 2014, a true and correct copy of the foregoing has been served upon the following counsel of record via electronic means:

Matthew M. Wolf (matthew.wold@aporter.com)
Edward Han (ed.han@aporter.com)
John E. Nilsson (john.nilsson@aporter.com)
Seth I. Heller (seth.heller@aporters.com)
Arnold & Porter LLP
555 Twelfth Street NW
Washington, DC 20004

/s/ Heather D. Redmond
Attorney for Plaintiff-Appellee